

Claims

1. A composition containing a very low water-soluble drug, which composition is produced by treating, with a supercritical or subcritical carbon dioxide fluid, a mixture containing a very low water-soluble drug and a porous material (exclusive of a porous silica material characterized in that the material has an average pore diameter of 1 to 20 nm, the total pore volume of the material that have a diameter falling within a range of $\pm 40\%$ of the average pore diameter account for 60% or more the volume of all the pores of the material, and, when subjected to X-ray diffractometry, the material exhibits one or more peaks at a diffraction angle (2θ) corresponding to d of 1 nm or more).

2. The composition containing a very low water-soluble drug according to claim 1, wherein the porous material is a porous carbon material, a porous aluminum material, or a porous silicon material.

3. The composition containing a very low water-soluble drug according to claim 1, wherein the porous material is a porous silicon material.

4. The composition containing a very low water-soluble drug according to claim 3, wherein the porous silicon material is light anhydrous silicic acid, hydrated silicon dioxide, silicon dioxide, or calcium silicate.

5. The composition containing a very low water-soluble drug according to any one of claims 1 through 4, wherein the

porous material has an average pore diameter of 1 to 1,000 nm.

6. The composition containing a very low water-soluble drug according to any one of claims 1 through 4, wherein the porous material has an average pore diameter of 2 to 500 nm.

7. The composition containing a very low water-soluble drug according to any one of claims 1 through 4, wherein the porous material has an average pore diameter of 2 to 200 nm.

8. The composition containing a very low water-soluble drug according to any one of claims 1 through 7, wherein the porous material has a specific surface area of 1 to 2,000 m²/g.

9. The composition containing a very low water-soluble drug according to any one of claims 1 through 7, wherein the porous material has a specific surface area of 100 to 1,800 m²/g.

10. The composition containing a very low water-soluble drug according to any one of claims 1 through 7, wherein the porous material has a specific surface area of 200 to 1,500 m²/g.

11. The composition containing a very low water-soluble drug according to any one of claims 1 through 10, wherein the ratio by weight of the very low water-soluble drug to the porous material is 1:0.1 to 1:1,000.

12. The composition containing a very low water-soluble drug according to any one of claims 1 through 11, wherein the very low water-soluble drug is 2-benzyl-5-(4-chlorophenyl)-6-[4-(methylthio)phenyl]-2H-pyridazin-3-one or prednisolone

valerate acetate.

13. A drug product comprising a composition containing a very low water-soluble drug as recited in any one of claims 1 through 12.

14. A method for producing a composition containing a very low water-soluble drug as recited in any one of claims 1 through 12, which method comprises placing, in a pressure-resistant vessel, a very low water-soluble drug and a porous material (exclusive of a porous silica material characterized in that the material has an average pore diameter of 1 to 20 nm, the total pore volume of the material that have a diameter falling within a range of $\pm 40\%$ of the average pore diameter account for 60% or more the volume of all the pores of the material, and, when subjected to X-ray diffractometry, the material exhibits one or more peaks at a diffraction angle (2θ) corresponding to d of 1 nm or more); filling the vessel with carbon dioxide; maintaining the temperature and pressure in the vessel at a temperature and pressure such that the carbon dioxide assumes the form of supercritical or subcritical fluid, thereby treating the drug and the porous material with the supercritical or subcritical carbon dioxide fluid; and subsequently discharging the carbon dioxide fluid from the vessel, followed by collection of the resultant composition.

15. The method for producing a composition containing a very low water-soluble drug according to claim 14, wherein the ratio by weight of the very low water-soluble drug to the

supercritical or subcritical carbon dioxide fluid is 1:1 to 1:1,000,000.

16. The method for producing a composition containing a very low water-soluble drug according to claim 14 or 15, wherein the temperature for treatment with the supercritical or subcritical carbon dioxide fluid is -40 to 100°C.

17. The method for producing a composition containing a very low water-soluble drug according to any one of claims 14 through 16, wherein the pressure for treatment with the supercritical or subcritical carbon dioxide fluid is 1 to 50 MPa.

18. The method for producing a composition containing a very low water-soluble drug according to any one of claims 14 through 17, wherein the time for treatment with the supercritical or subcritical carbon dioxide fluid is one minute to 24 hours.

19. The method for producing a composition containing a very low water-soluble drug as recited in any one of claims 1 through 12, which method comprises placing, in a pressure-resistant vessel, a very low water-soluble drug and a porous material (exclusive of a porous silica material characterized in that the material has an average pore diameter of 1 to 20 nm, the total pore volume of the material that have a diameter falling within a range of $\pm 40\%$ of the average pore diameter account for 60% or more the volume of all the pores of the material, and, when subjected to X-ray diffractometry, the material exhibits one or more peaks at a diffraction

angle (2θ) corresponding to d of 1 nm or more); maintaining the temperature in the vessel at a temperature at which carbon dioxide is in a supercritical or subcritical state; filling the vessel with carbon dioxide so as to attain a pressure such that the carbon dioxide assumes the form of supercritical or subcritical fluid; treating the drug and the porous material with the supercritical or subcritical carbon dioxide fluid; and subsequently discharging the carbon dioxide fluid from the vessel, followed by collection of the resultant composition..

20. The method for producing a composition containing a very low water-soluble drug according to claim 19, wherein the ratio by weight of the very low water-soluble drug to the supercritical or subcritical carbon dioxide fluid is 1:1 to 1:1,000,000.

21. The method for producing a composition containing a very low water-soluble drug according to claim 19 or 20, wherein the temperature for treatment with the supercritical or subcritical carbon dioxide fluid is -40 to 100°C.

22. The method for producing a composition containing a very low water-soluble drug according to any one of claims 19 through 21, wherein the pressure for treatment with the supercritical or subcritical carbon dioxide fluid is 1 to 50 MPa.

23. The method for producing a composition containing a very low water-soluble drug according to any one of claims 19 through 22, wherein the time for treatment with the

supercritical or subcritical carbon dioxide fluid is one minute to 24 hours.